

# How to revise an existing Study Document

Note: You need to be in a submission form such as an Initial Review Submission Form, a Change Request & Amendments Form, or a Review Response Submission Form to revise an existing study document.

Also, please do not upload zip files or any files that the IRB will not be able to open without a special software.

Note: If you want to modify an existing document, do not add it as a new document. Instead, make a revision of the existing document .

Select or Revise Existing		Add a New Document			Add Multiple Documents		
Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	View Document
No Documents have been attached to this form.							

If you haven't already done so, click on the "Select or Revise Existing" button to open the "Select Existing or Create Revised Study Document" popup.

The “Select Existing or Create Revised Study Document” popup will open.

First you need to find the document that you want to revise. If you have many documents, you can use the filter fields to search for a specific document by selecting one or more filters then clicking on “Filter Documents”. Or you can just scroll down to find it. (yellow arrows)

**Select Existing or Create Revised Study Document** ✕

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category: --none--      Title:

Version #:  .       Search level:  Top  All

Version Date:  between       Expiration Date:  between

Document Outcome: --none--

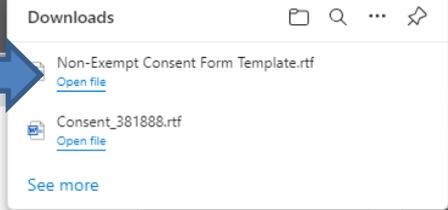
43 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Sponsor Version	Download Document for Editing	Title	Expiration Date	Document Outcome	View Document	Upload Revised Document	
								Category					
				1.6	08/09/2021			C4R IRB Protocol, with FHS at BUSM specifics			442.52 KB		
				1.1	06/01/2023			C4R FHS Exempt Information Sheet - Spanish		Approved and Stamped	169.76 KB		
				1.0	05/30/2023			C4R FHS Exempt Information Sheet (Wave 3) English <i>*Added by the IRB</i>		Approved and			

Once you locate the document that you want to revise:

- It is recommended that you download a copy of that document from INSPIR for editing. You can download it by clicking on “Download Document for Editing” icon (orange arrow) then proceed to the next slide.
- If you already have the revised document on your computer ready to be uploaded, skip the next slide to slide # 5.

1. The selected study document will download. Depending on your web browser, you will get the “Downloads” popup similar to this one. Click on the file to open it.



Document Outcome: --none--

Add a New Document Filter Documents

43 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Sponsor Version	Download Document for Editing	Title	Expiration Date	Document Outcome	View Document	Upload Revised Document
								Category				
				1.6	08/09/2021			C4R IRB Protocol, with FHS at BUSM specifics Protocol			442.52 KB	
				1.1	06/01/2023			C4R FHS Exempt Information Sheet - Spanish Exempt Information Sheet		Approved and Stamped	169.76 KB	
				1.0	05/30/2023			C4R FHS Exempt Information Sheet (Wave 3) English *Added by the IRB Exempt Information Sheet		Approved and Stamped	187.03 KB	
				1.0	04/07/2023			FHS SPANISH C4R Wave 3 Email and Text to participants short version_ *Added by the IRB Recruitment/Advertising		Approved	16.63 KB	
				1.0	05/19/2023			Translator Qualification Form Wave 3 Activities *Added by the IRB Translator Qualifications Form		Approved	51.71 KB	
				1.0	04/07/2023			SPANISH_C4R COVID-19 Wave 3 Questionnaire Recruitment I ntroductory Scripts_04.07.2023 (short version) *Added by the IRB				

Save the study document to your computer then start making your changes. Don't forget to save it again when you're done editing. Proceed to the next slide if you are ready to upload the revised study document.

Once you have finished revising the study document on your computer and it's ready to be uploaded, click on the "Upload Revised Document" icon (green arrow).

### Select Existing or Create Revised Study Document



If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category:

Version #:  .

Version Date:  between

Document Outcome:

Title:

Search level:  Top  All

Expiration Date:  between

Add a New Document

Filter Documents

43 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Sponsor Version	Download Document for Editing	Title Category	Expiration Date	Document Outcome	View Document	Upload Revised Document
				1.6	08/09/2021			C4R IRB Protocol, with FHS at BUSM specifics Protocol			442.52 KB	
				1.1	06/01/2023			C4R FHS Exempt Information Sheet - Spanish Exempt Information Sheet		Approved and Stamped	169.76 KB	
				1.0	05/30/2023			C4R FHS Exempt Information Sheet (Wave 3) English <i>*Added by the IRB</i> Exempt Information Sheet		Approved and Stamped	187.03 KB	

The “Study Document Revision” popup will open.

Notice that this revised document will now be given a new Version Number (the system will increment the version number by + .1) (yellow arrow)

**Study Document Revision:**

\*Document Title: C4R FHS Exempt Information Sheet - Spanish

\*Select the document to upload: Choose File No file chosen

Version Number: .2

Version Date: /2023

Sponsor Version:

\* Category: Exempt Information Sheet

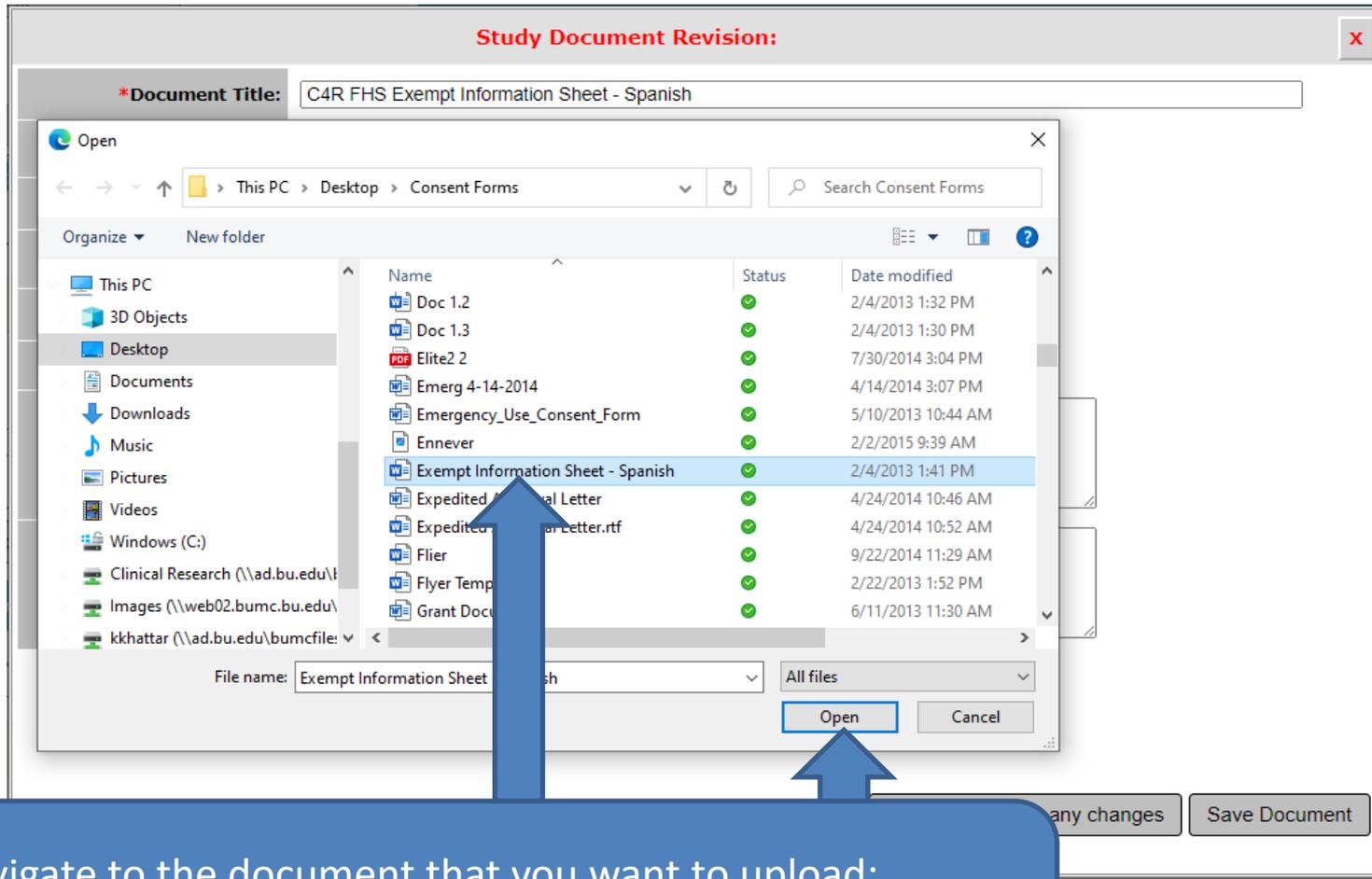
Description:

Comments:

Close, don't save any changes Save Document

Click on the “Choose File” button to navigate on your computer to where you last saved your revised study document to upload it (orange arrow)

This opens the “Open” pop-up or a different popup depending on the system that you are using.



1. Navigate to the document that you want to upload:
2. Click on the document to highlight it
3. Click on “Open”

This will bring you back to the “Study Document Revision:” popup.

- Notice the uploaded document’s name is now appearing in the popup (blue arrow)

1. Change the “Version Date” to today’s date (green arrow)
2. Click on the “Save Document” button (Grey arrow)

The screenshot shows a 'Study Document Revision' popup window. The form contains the following fields and controls:

- \*Document Title:** C4R FHS Exempt Information Sheet - Spanish
- \*Select the document to upload:** Choose File Exempt Info...panish.docx
- Version Number:** 1 .2
- Version Date:** 06/01/2023 (with a calendar icon)
- Sponsor Version:** (empty field)
- \* Category:** Exempt Information Sheet
- Description:** (empty text area)
- Comments:** (empty text area)

Annotations on the form:

- A blue arrow points to the document name 'Exempt Info...panish.docx' in the 'Select the document to upload' field.
- A green arrow points to the calendar icon next to the 'Version Date' field.
- A grey arrow points to the 'Save Document' button at the bottom right.

Buttons at the bottom: 'Close, don't save any changes' and 'Save Document'.

This will bring you back to the “Select Existing or Create Revised Study Document” popup.

- If you want to revise more study documents, repeat slides 3 – 9
- If you are done revising study documents, close this popup by clicking on the X icon (green arrow)



**Select Existing or Create Revised Study Document** X

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category:    
 Version #:    
 Version Date:  between    
 Document Outcome:

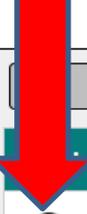
Title:    
 Search level:  Top  All   
 Expiration Date:  between

43 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Sponsor Version	Download Document for Editing	Title	Expiration Date	Document Outcome	View Document	Upload Revised Document
								Category				
				1.2	06/01/2023			C4R FHS Exempt Information Sheet - Spanish Exempt Information Sheet				
				1.6	08/09/2021			C4R IRB Protocol, with FHS at BUSM specifics Protocol				
				1.0	05/30/2023			C4R FHS Exempt Information Sheet (Wave 3) English Exempt Information Sheet		Approved and Stamped		
				1.0	04/07/2023			FHS SPANISH C4R Wave 3 Email and Text to participants short version_ Recruitment/Advertising		Approved		
				1.0	05/19/2023			Translator Qualification Form Wave 3 Activities Translator Qualifications Form		Approved		
				1.0	04/07/2023			SPANISH_C4R COVID-19 Wave 3 Questionnaire Recruitment I ntroductory Scripts_04.07.2023 (short version) Questionnaire		Approved		

This will bring you back to where you started in the form.

The revised Study Document that you have just uploaded should appear on this table/list. You can verify that you have uploaded the right document by clicking on the “View Document” icon to open it (yellow arrow). You can detach (not common) from this submission any document that you don’t want to submit to the IRB by clicking on the (X) icon next to it (red arrow).

Select or Revise Existing		Add a New Document		Add Multiple Documents			
	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	View Document
	1.2		C4R FHS Exempt Information Sheet - Spanish	Exempt Information Sheet			 168.27 KB

That’s it! You can start over if you have additional study documents to revise.